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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,327	09/02/2004	Shingo Hiramatsu	0210-0190PUS1	1247

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EXAMINER
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SAJJADI, FEREDYDOUN GHOTB

ART UNIT	PAPER NUMBER
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1633

NOTIFICATION DATE	DELIVERY MODE
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06/27/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,327	<b>Applicant(s)</b> HIRAMATSU ET AL.	
	<b>Examiner</b> FEREYDOUN G. SAJJADI	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24, 26-28 and 30-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-20, 40 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-24, 26-28, 30-39 and 42-45 is/are rejected.
- 7) ☒ Claim(s) 21-23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 31, 2008, and the amendment filed January 31, 2008, that includes a response to the final office action dated October 31, 2007, have been entered. Claims 1-24, 26-28 and 30-45 are pending in the application. Claims 21-23 have been amended. No claims were cancelled, or newly added. Claims 1-20, 40, and 41 remain withdrawn from further consideration, with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 21-24, 26-28, 30-39 and 42-45 are under current examination.

#### ***Response to Claim Objections***

Claim 31 was newly objected to in the office action dated October 31, 2007 for minor informalities. In view of Applicants' amendment of the claim, obviating the ground for objection, the objection is hereby withdrawn.

#### ***New Claim Objections***

Claims 21-23 are newly objected to for claiming nucleotide sequences considered essential subject matter by reference to nucleotides 57444 to 62927 of GenBank Accession No. AF 226688. Such is improper and not in compliance with sequence rules 37 CFR 1.821-1.825; and further not in compliance with 37 CFR 1.57. Applicants should note that in the absence of SEQ ID NOS for 10 or more nucleotides, the search of sequences by the USPTO is precluded.

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In the instant case, nucleotides 57444 to 62927 of GenBank Accession No. AF 226688 appear to correspond to nucleotides 1 to 5484 of SEQ ID NO: 23. Appropriate correction is required.

***New Claim Rejections - 35 USC § 112- New Matter***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicants' claim amendments have necessitated the following new grounds of rejection.

Claim 21-23 are newly rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art (hereafter the Artisan), that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR §1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

**Comment [a1]:** For RCE practice, we do not make the RCE Final if new rejections are added, particularly new matter rejections. Look at it this way, if they had filed this as an after-final you would not have entered it and so the RCE gives them the opportunity for additional consideration.

Claims 21-23 recite the limitation of the following elements in order: "(2) an approximately 5500 base pair sequence comprising nucleotides 57444 to 62927 of GenBank Accession No. AF 226688; (3) a fibroin H chain gene promoter expressed in *Bombyx mori* silk glands". The instant specification is devoid of any such description for the claimed limitation, as the specification fails to disclose the approximately 5500 bp sequence in tandem with a fibroin gene promoter (i.e. resulting in an overlapping, partially duplicated fibroin H chain gene promoter). Applicants state that support for the amendment can be found in Examples 18 and 19, and on pp. 54-57 of the specification. However, the specification fails to provide support for a partially duplicated promoter region and only discloses an expression comparison between a gene cassette containing the 5.5 kb fibroin H chain 5' terminal region and a cassette containing the fibroin H chain 5' terminal promoter region.

The specification, while disclosing SEQ ID NO: 23, that encompasses nucleotides 57444 to 62927 of GenBank Accession No. AF 226688, fails to disclose the partial duplication of the

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fibroin H chain gene promoter or its corresponding expression in a single gene cassette. Thus, the disclosure of the specification is not synonymous with the limitation of the instant claim.

Hence, at the time the application was filed, an Artisan of skill would not recognize from the disclosure that Applicant was in possession of a gene cassette comprising a partially duplicated and overlapping fibroin H chain gene promoter, as claimed.

This is a new matter rejection.

***Response to Claim Rejections - 35 U.S.C. § 103***

Claims 21-24, 26-28, 30-39 and 42-45 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al., US 2002/0137211 in view of Zhao et al. (Acta Biochimica et Biophysica Sinica 33(1): 112-116, Jan. 2001); Zhang et al. (Acta Biochimica et Biophysica Sinica 31(2): 119-123, 1999) and GenBank Acc. No. AF226688. The rejection set forth on pp. 4-8 of the previous office action dated October 31, 2007 is maintained for claims 21-24, 26-28, 30-39 and 42-45, for the reasons of record.

Applicants do not agree and argue that claims 21-23 have been amended to additionally recite, in part, (2) an approximately 5500 base pair sequence comprising nucleotides 57444 to 62927 of GenBank Accession No. AF 226688, and that none of the cited references disclose or fairly suggest this unique feature, and the claimed gene cassette is limited to only that which provides a high expression of an exogenous protein. Further arguing that a gene cassette after the amendment, i.e., HUP- IC-HA which contains an approximately 5500 base pair sequence comprising nucleotides 57444 to 62927 of GenBank Accession No. AF 226688, and a gene cassette before the amendment, i.e., HP-IC-HA which does not contain an approximately 5500 base pair sequence comprising approximately nucleotides 57444 to 62927 of GenBank Accession No. AF 226688" were compared in Example 18, showing that HUP- IC-HA is clearly superior in comparison with a gene cassette before the amendment, i.e., "HP-IC-HA" which does not contain an approximately 5500 base pair sequence comprising approximately nucleotides 57444 to 62927 of GenBank Accession No. AF 226688. Applicants' arguments have been fully considered, but are not found persuasive.

Applicants' analysis and conclusions are clearly in error, because nucleotides 57444 to 62927 of GenBank Accession No. AF 226688 corresponds to nucleotides 1 to 5484 of SEQ ID NO: 23, previously examined in rejected claim 26. Applicants' arguments are based on the false assumption that prior to the instant claim amendments, the examination of the claimed fibroin H chain gene promoter was somehow limited to the HP-IC-HA segment of the promoter. However, such is clearly not the case. As previously indicated on the record, Zhao discloses a transgenic silkworm with a genome comprising a "gene cassette" embraced by the instant claims. The gene cassette comprises, in order, the 5' end of the endogenous fibroin H-chain gene, including the promoter. The structural organization and sequence of the *Bombyx mori* fibroin heavy chain gene and its promoter was known in the prior art as GenBank Accession No. AF 226688, and there is no reason for a person of ordinary skill in the art to utilize a minimal promoter region with low expression activity as part of a gene cassette to express a gene of interest in the silk gland. A person of ordinary skill in the art having utilized the promoter sequences as set forth in SEQ ID NO: 23 in a gene cassette would necessarily include nucleotides 57444 to 62927 of GenBank Accession No. AF 226688.

Thus, the rejection of claims 21-24, 26-28, 30-39 and 42-45 is maintained, for reasons of record, and the foregoing commentary.

### ***Conclusion***

**Claims 21-24, 26-28, 30-39 and 42-45 are not allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/

Fereydoun G. Sajjadi, Ph.D.  
Examiner, Art Unit 1633